K042784

DEC 1 0 2004

# 510(k) Summary

OFFICIAL CONTACT:

John M Kiste
Regulatory Affairs Specialist
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 ext. 3444

CLASSIFICATION NAME: Injector with Syringe, Angiographic

COMMON NAME(S): Powered Injector with Syringe

PROPRIETARY NAME: Medrad Spectris Solaris EP MR Injector System

PREDICATE DEVICE: Medrad Spectris Solaris MR Injector System (3T Compatible) (K033247)

INTENDED USE: The Spectris Solaris EP MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures. Only trained healthcare professionals are intended to operate this device.

DEVICE DESCRIPTION AND COMPARISON TO PREDICATE:

The Medrad Spectris Solaris EP MR Injection System maintains the same intended use, similar operational parameters, similar labeling and is essentially used in a manner similar to the predicate device.

The Spectris Solaris EP MR Injector is comprised of the same two main components as the predicate device - Injector Head/Stand (HSU) and Display Control Unit (DCU). Differences between the predicate device and the new Spectris Solaris EP MR Injector are detailed in the table below. The following Comparison Matrix identifies the similarities and differences between the new device and the predicate device.

| **Feature: Injector System** | **Medrad Spectris Solaris MR Injector (3T Compatible) (K033247) Predicate** | **Medrad Spectris Solaris EP MR Injector** |
|---|---|---|
| Flow Rate Injector | 1 ml/sec to 10 ml/sec +/-(10%+/-0.02 ml/sec)<br><br>0.01ml/sec to 0.99ml/sec +/-(10%+0.005ml/sec) | Same |

| Feature:<br>Injector System | Medrad Spectris Solaris MR Injector (3T Compatible) (K033247) Predicate | Medrad Spectris Solaris EP MR Injector |
|---|---|---|
| Fractional volumes | Yes | Same |
| Remote Information Display | Color Touch screen | Same |
| Multi-Phase | 6 | Same |
| Protocol Storage Capability | Yes; 3 step procedure<br>32 protocols | Same |
| Hold Capability | Yes | Same |
| Safety Stop Mechanism | Yes | Same |
| Syringe System | 2 total, 1– 115 ml syringe and 1- 65 ml syringe | Same |
| Air Detection Device | User observable | Same |
| Syringe Sensing | Yes | Same |
| Volume Remaining Readout | Graduation on syringe; LCD on Program Panel | Same |
| Programmed Volume | Yes, 1 to 63 ml and 1-115 ml | Same |
| Fill Rate | Configurable up to a maximum of 10 ml/sec | Same |
| Flow Rate | Variable | Same |
| KVO | Yes; 0.25 ml, time adjustable. Defaults at every 30 sec. | Same |
| Pressure Limit | 311 PSI for Syringe A<br>310 PSI for Syringe B | Same |
| Start/Stop switch | Yes, Located at injector head or at display unit. | Same |
| Communication | Fiber Optic | Same |
| System Compatibility | 0.2 – 3 T | Same |

| Feature:<br>Disposable System | | |
|---|---|---|
| **Syringe System** | **2 total, 1– 115 ml syringe and 1-65 ml syringe, 2 - 65 ml syringes** | |
| Intended Use | Saline/Contrast delivery | Same |
| Barrel Material Composition | PET | Same |
| Barrel length | 4.5" | Same |
| Barrel OD | 1.565" | Same |
| Barrel ID | 1.415 | Same |
| Plunger Material Composition | Polycarbonate | Same |
| Barrel Flange | Quik-Fit Design | Same |
| Packaging | Polystyrene tray with Tyvek Lid | Same |
| Sterilization | Ethylene Oxide | Same |
| **Medrad –T connector** | | |
| T-connector | Polycarbonate | Same |
| Tubing | PVC | Same |
| Luer Fitting | Polycarbonate | Same |
| Length | 96" | Same |
| Tubing ID | 0.075" | Same |
| Maximum Pressure | 350 PSI | Same |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2004

Medrad, Inc.
c/o Mr. John M. Kiste
Regulatory Affairs Specialist
One Medrad Drive
Indianola, PA 15051

Re: K042784
Medrad Spectris Solaris MR Injector System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: November 9, 2004
Received: November 10, 2004

Dear Mr. Krite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number:** K042784

**Device Name:** Medrad Spectris Solaris EP MR Injector

**Indications for Use:**

The Spectris Solaris EP MR Injection System is a syringe-based fluid delivery system indicated for delivery of contrast media during MR applications. It is intended to be used for the specific purpose of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures. Only trained healthcare professionals are intended to operate this device.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

AND/ OR

Over-The-Counter Use ____ (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE ON THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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